NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

25 November 2021

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Prof. Cathal O'Donnell	Deputy Chairperson, NREC-MD
Dr Caitriona Cahir	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Dr Owen Doody	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Prof. Susan O'Connell	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Ms Riona Tumelty	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Prof. Anne Parle-McDermott	Member, NREC-MD
Prof. Declan Patton	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees

Dr Jennifer Ralph James Head, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Prof. Therese Murphy, Dr Paul O'Connor

Quorum for decisions: Yes

Agenda

- Welcome & apologies
- NREC Committee Business Report
- Minutes of previous meeting (28 October 2021) & matters arising
- Research in emergency settings
- Declarations of interest
- Application 21-NREC-MD-014
- Application 21-NREC-MD-015
- Application 21-NREC-MD-04-SA
- Application 21-NREC-MD-012-SA
- AOB

- The Chairperson welcomed the Committee and opened the meeting.
- NREC Committee Business Report: The Committee *noted* the report.
- Minutes of previous meeting (28 October 2021) & matters arising: The minutes were *approved*.
- The Programme Manager presented an overview of the approach to consent requirements in clinical investigations in emergency situations as set out by Article 68, Medical Device Regulation (MDR; EU No. 2017/745). The NREC-MD proposed this information is added to the National Office website.
- Declarations of interest: *none*

Applications

21-NREC-MD-014

- Principal Investigator: Dr Martin Buckley,
- Study title: Randomised, single dose, crossover, open label, placebo controlled, single site confirmatory clinical investigation in patients with gastro-oesophageal reflux, to characterise the acid neutralisation activity of a calcite chewing gum, using oesophageal ambulatory pH monitoring.
- Lead institution: Gastroeterology/ GI Physiology Laboratory, Mercy University Hospital, Grenville Place, Centre, Cork, T12 WE28.
- NREC-MD comments
    - The NREC-MD noted that this application pertains to a randomised, single dose, crossover, open label, placebo controlled, single site clinical investigation of a calcite

chewing gum, a class III pre-market device, in patients with gastro-oesophogeal reflux disease.

- NREC-MD decision
  - *Request for further information*
- Further information requested
  - The NREC-MD requests that a copy of the contract/ trial agreement is provided.
  - The NREC-MD requests more information on the grounds and process for termination of the investigation
  - The NREC-MD requests more information on participant recruitment.
  - The NREC-MD requests more information on inclusion/ exclusion criteria for potential participants with food allergies or dietary preferences.
  - The NREC-MD requests that the PIL is revised for clarity and accessibility in lay terminology; includes information about the restrictions in medication and lifestyle; and includes email address of the PI along with the phone number.
  - The NREC-MD requests the informed consent form is revised to ensure compliance with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018). For example, participants need to provide explicit consent for their data to be transferred and processed outside of the EU (including Northern Ireland).
  - The NREC-MD requests the sum allocated for expenses is revised to allow for wider range of travel/ parking cost.
  - The NREC-MD requests clarity on the proposed data processing and retention as a part of the study to ensure compliance with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018), specifically in relation to access to medical records, retention period, data minimisation and withdrawal process.
  - The NREC-MD requests that details of the Data Monitoring Committee are provided.
  - The NREC-MD requests a revised comprehensive DPIA compiled with an input from the site DPO.

21-NREC-MD-015

- Principal Investigator: Professor Robert A Byrne
- Study title: Fractional Flow Reserve or 3D-Quantitative-Coronary-Angiography Based Vessel-FFR guided revascularization
- Lead institution: Cardiology Department, Mater Private Hospital, 73 Eccles Street, Dublin 7, D07 KWR1.
- NREC-MD comments
  - The NREC-MD noted this clinical investigation aims to determine the safety and effectiveness of a vFFR guided strategy versus an invasive FFR guided strategy to guide coronary revascularization in patients with intermediate coronary artery stenosis.

- The NREC-MD noted that this clinical investigation is to be carried out in two Mater Private sites in Dublin and Cork.

- NREC-MD decision
  - *Request for further information*
- Further information requested
  - The NREC-MD requests a clarification of the roles and responsibilities of the entities involved in this project.
  - The NREC-MD requests that the timelines on CTA are updated, along with insurance and liability policies.
  - The NREC-MD requests that participants are not charged for their participation in the study.
  - The NREC-MD requests a clarification on whether participant travel expenses will be reimbursed.
  - The NREC-MD requests clarification on target sample size, rather than approximate sample size.
  - NREC-MD requests a clarification on the ad hoc procedures outlined in Study synopsis and that all related documentation is submitted.
  - The NREC-MD requests that the PIL is revised for clarity and accessibility in lay terminology.
  - The NREC-MD requests that the PIL highlights that one of the procedures is more invasive and potentially more uncomfortable.
  - The NREC-MD requests the informed consent form is revised to ensure compliance with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
  - The NREC-MD requests that details of the Data Monitoring Committee are provided.
  - The NREC-MD requests justification of data retention period of 15 years.
  - The NREC-MD requests clarification on whether participant data will be anonymised or pseudoanonymised.
  - The NREC-MD requests that access to participant medical records and any data processing is conducted in line with the Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018).
  - The NREC-MD requests that the radiation section of the form is completed.

21-NREC-MD-004-SA

- Principal Investigator: Professor James Loughman
- Study title: MyopiaX Treatment for the Reduction of Myopia Progressionin Children and Adolescents: Safety and Efficacy Investigation (Substantial Amendment)
- Lead institution: Center for Eye Research Ireland (CERI), Technological University Dublin, Dublin 7.
- NREC-MD comments

  - The NREC-MD noted that the original study received a favourable opinion from the NREC-MD on 30/07/2021, and that the present application relates to a substantial amendment. In this regard, the NREC-MD opinion pertains only to the substantial amendment outlined in the application submitted to the National Office.
- The NREC-MD notes that this substantial amendment relates to a change in
  - Instructions for Use (IFU)
  - Assent document for adolescents
  - Privacy policy of the app usage
  - Appendix 1 of the Protocol
  - Visual Habits Questionnaire
  - Advertising material to support recruiting
- NREC-MD decision
  - *Favourable*

21-NREC-MD-012-SA

- Principal Investigator: Dr Stephen O'Connor
- Study title: RHEIA (Randomized researcH in womEn all comers wIth Aortic stenosis) A Prospective, Randomized, Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Transcatheter Aortic Valve Implantation in Female Patients who have Severe Symptomatic Aortic Stenosis Requiring Aortic Valve Replacement
- Lead institution: St. James´s Hospital, Department of Cardiology, Respiratory and Cardio-Thoracic surgery, James´s Street, D08 NHY1 Dublin
- NREC-MD comments
  - The NREC-MD noted that the original study received a favourable opinion from the SJH/TUH Joint Research and Ethics Committee on 17/08/2020, and that the present application relates to a substantial amendment outlined in the application submitted to the National Office.
- The NREC-MD notes that this substantial amendment relates to a change in an update to:
  - Clinical study protocol
  - Administrative changes in the members of Data Safety Monitoring Board due to retirements or workload was done.
- NREC-MD decision
  - *Favourable*

- AOB:
  - The Committee agreed to hold a division meeting on 13 December to review responses to applications 21-NREC-MD-013, 21-NREC-MD-14 and 21-NREC-MD-

015, should the applicants respond to the requests for further information within 14 days.

- The Programme Manager updated the Committee on the topics of upcoming “lunch and learn” programme sessions.
- The Committee discussed the introductory meeting between the NRECs and the Department of Health held on 11/11/2021 formal letters of appointment, terms of reference, and details of indemnity, are still pending.
- The Head of the National Office thanked the Committee for their enthusiasm for and commitment to their role as members of the National Research Ethics Committee for Clinical Investigations of Medical Devices since its launch in May this year.

- The Chairperson thanked the Committee and closed the meeting.